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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Personalized tumor vaccine and use thereof for cancer immunotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the (U.S.) Patents and Patent Applications listed in the Supplementary Information section of this notice to NE1 Inc, located at 515 Madison Avenue, 8th Fl. Suite 8096 New York, NY 10022.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Dr. Berna Uygur, Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5530; E-mail: berna.uygur@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

(United States Provisional) Patent Application No. 62/946,934, filed on December 11, 2019 and entitled "Personalized Tumor Vaccine and Use Thereof for Cancer Immunotherapy" [HHS Reference No. E-003-2020/0-US-01].

(PCT) Patent Application No. PCT/US2020/064412, filed on December 11, 2020 and entitled "Personalized Tumor Vaccine and Use Thereof for Cancer Immunotherapy" [HHS Reference No. E-003-2020/0-PCT-02].

The patent rights in this invention are co-owned by a) the United States of America, as represented by the Secretary, Department of Health and Human Services, b) University of South Bohemia, and c) NE1 Inc. The prospective exclusive license territory may be worldwide, and the field of use may be limited to: Development, manufacture, and commercialization of the MBTA Therapy Products, as claimed in the Licensed Patent Rights, for the treatment of cancer in humans.

This technology discloses "MBTA Therapy Product(s)" which are vaccine products comprising irradiated tumor cells pulsed with phagocytic agonists (Mannan-BAM, a polysaccharide derivative of mannan), TLR (Toll-like receptor) ligands, and Anti-CD40-monoclonal antibody. The MBTA Therapy Products may be used as personalized tumor vaccines to treat cancer.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments

and objections, other than those in the form of a license application, will not be treated

confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to

contain business confidential information and any release of information in these license

applications will be made only as required and upon a request under the Freedom of

Information Act, 5 USC 552.

Dated: October 1, 2021.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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